

## **BISMATROL - bismuth subsalicylate liquid**

### **Major Pharmaceuticals**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Maximum Strength Bismatrol**

#### **Active ingredient (in each 15 mL tbsp)**

Bismuth subsalicylate 525 mg

#### **Purpose**

Upset stomach reliever and anti-diarrheal

#### **Uses**

relieves:

- diarrhea
- heartburn
- indigestion
- nausea
- upset stomach associated with these symptoms

#### **Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

#### **Allergy alert: Contains salicylate. Do not take if you are**

- allergic to salicylates (including aspirin)
- taking other salicylate products

#### **Do not use if you have**

- bloody or black stool
- an ulcer
- a bleeding problem

#### **Ask a doctor before use if you have**

- fever
- mucus in the stool

#### **Ask a doctor or pharmacist before use if you are**

- taking any drug for
- anticoagulation (thinning of the blood)
- diabetes
- gout

- arthritis

### **When using this product**

a temporary, but harmless darkening of the stool and/or tongue may occur

### **Stop use and ask a doctor if**

- symptoms get worse
- ringing in the ears or loss of hearing occurs
- diarrhea lasts more than 2 days

**If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison control center immediately.

### **Directions**

- **shake well before use**
- for accurate dosing, use dose cup
- adults and children 12 years and over: 1 dose (2 tbsp or 30 mL) every hour as needed
- do not exceed 4 doses (8 tbsp or 120 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

### **Other information**

- each Tbsp contains: sodium 5 mg, salicylate 236 mg, potassium 15 mg
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)
- **TAMPER EVIDENT: Do not use if imprinted shrinkband is missing or broken.**

### **Inactive ingredients**

benzoic acid, D&C red 22, D&C red 28, flavor, hydroxy ethyl cellulose, potassium hydroxide, purified water, saccharin sodium, salicylic acid, simethicone, xanthan gum.

### **Principal Display Panel**

Maximum Strength Bismatrol

Soothing, coating action provides

fast relief for heartburn, indigestion, nausea, upset stomach and diarrhea

compare to the active ingredient in pepto-bismol<sup>®</sup> maximum strength

8 FL OZ (236 mL)

Maximum Strength Bismatrol



Product Characteristics				
Color	pink		Score	
Shape			Size	
Flavor	WINTERGREEN		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-1314-09	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2009	12/31/2021
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part335		01/05/2009	12/31/2021

**Labeler** - Major Pharmaceuticals (191427277)

**Registrant** - Guardian Drug Company (119210276)

Establishment			
Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	manufacture(0904-1314)